

K041761

JUL 13 2004

**INFINITT**

### 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

May 20, 2004

Submitter's Information: 21 CFR 807.92(a)(1)

Mr. Samuel Choi, Director  
INFINITT CO., LTD  
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	RapidiaColon™ System
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807.92(a)(3)

RapidiaColon™ system is substantially equivalent to the:

Manufacturer:	Voxar Limited Bonnington Bond, 2 Anderson Place Edinburgh, UK EH6 5 NP
Device Name:	plug 'n view 3d, version 1.0
510(k) Number:	K 992654
Decision Date:	11/05/1999
Decision:	Substantially Equivalent
Panel Code reviewed by:	Radiology
Panel Code classified by:	Radiology
Product Code:	LLZ
Device Classification Name:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number:	Class II - 892.2050

Device Description: 21 CFR 807.92(a)(4)

RapidiaColon™ is a software device for 3D (three dimensional) and 2D (two dimensional) viewing and manipulation of digital DICOM compliant images using graphics rendering technology. The software device provides 3D volume rendering (VR), multi-planar reconstruction (MPR), virtual endoscopy, and issues reports.

Indications for Use: 21 CFR 807.92(a)(5)

RapidiaColon™ is a software application for the display and 3D visualization of medical data derived from digital modalities (CT and MRI scanners). It is intended

for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print, and distribute DICOM compliant image studies using standard PC hardware.

Technological Characteristics: 21 CFR 807 92(a)(6)

The proposed and predicate devices are both software programs that can be used for manipulation of DICOM-compliant CT images. The proposed and predicate software can be operated from a personal computer. Differences between the proposed and predicate devices are limited to the availability of certain image viewing and editing features.

The proposed RapidiaColon software conforms to DICOM (Digital Imaging and Communications in Medicine) Version 3. Validation testing was provided that confirms that RapidiaColon performs all input functions, output functions, and all required actions according to the functional requirements specified in the Software Requirements Specification (SRS).

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for the RapidiaColon™ device contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.

The RapidiaColon™ device has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "minor".



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUL 13 2004

INFINITT Co., Ltd.  
% Mr. N. E. Devine, Jr.  
Responsible Third Party Official  
Entela, Inc.  
3033 Madison Ave. SE  
GRAND RAPIDS MI 49548

Re: K041761  
Trade/Device Name: RapidiaColon™  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communications system  
Regulatory Class: II  
Product Code: 90 LLZ  
Dated: June 14, 2004  
Received: June 30, 2004

Dear Ms. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

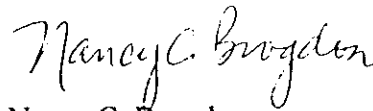
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K041761

Device Name: RapidiaColon™

### Indications for Use:

RapidiaColon™ is a software application for the display and 3D visualization of medical data derived from CT and MRI scanners. It is intended for use by radiologists, clinicians and referring physicians to acquire, process, render, review, store, print, and distribute DICOM compliant image studies using standard PC hardware

Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K041761